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Cardiac Stimulation Devices and Methods for Measuring Impedances Associated with the Left Side of the Heart

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RELATED APPLICATION

This application stems from and claims priority to U.S. Provisional Application Serial No. 60/204,310, filed on May 15th, 2000, the disclosure of which is incorporated by reference herein.

TECHNICAL FIELD

The present invention generally relates to cardiac rhythm management devices, such as implantable cardioverter-defibrillators (ICDs) and pacemakers, or combinations thereof. The present invention more particularly relates to such devices which utilize one or more electrodes implanted on the left-side of the heart for providing desired stimulation therapy and for measuring physiological parameters based on measured electrical impedances.

BACKGROUND

Cardiac rhythm management devices, including implantable devices, are well known in the art. Such devices may include, for example, implantable cardiac pacemakers, cardioverters or defibrillators. The devices are generally implanted in an upper portion of the chest, in either the left or right side depending on the type of the device, beneath the skin of a patient within what is known as a subcutaneous pocket. The implantable devices generally function in association with one or more electrode-carrying leads which are implanted within the heart. The electrodes are typically positioned within the right side of the heart, either the right ventricle or right atrium, or both, for making electrical contact with their designated heart chamber. Conductors within the leads couple the electrodes to the device to enable the device to deliver the desired stimulation therapy.

Traditionally, therapy delivery has been limited to the right side of the heart. The reason for this is that implanted electrodes can cause blood clot formation in some patients. If a blood clot were released from the left-side of the heart, as from the left ventricle, it could pass directly to the brain resulting in a paralyzing or fatal stroke. However, a blood clot released from the right side of the heart, as from the right ventricle, would pass into the lungs where the filtering action of the lungs would prevent a fatal or debilitating embolism in the brain.

Recently, new lead structures and methods have been proposed and even practiced for delivering cardiac rhythm management therapy from or to the left-side of the heart. These lead structures and methods avoid electrode placement within the left atrium and left ventricle of the heart by lead implantation within the coronary sinus and/or the great vein of the heart which communicates with the coronary sinus and extends down towards the apex of the heart. As is well known, the coronary sinus passes closely adjacent the left atrium and extends into the great vein adjacent the left ventricular free wall. The great vein then continues adjacent the left ventricle towards the apex of the heart.

It has been observed that electrodes placed in the coronary sinus and great vein may be used for left atrial pacing, left ventricular pacing, and even cardioversion and defibrillation. This work is being done to address the needs of a patient population with left ventricular dysfunction and congestive heart failure. This patient class has been targeted to receive pacing leads intended for left ventricular pacing, either alone or in conjunction with right ventricular pacing. When delivering such therapy to these patients, it would be desirable to provide device-based measurements of left ventricular function for both monitoring and therapy delivery.

It is known in the art that device-based impedance measurements offer one method for assessing patient condition. It is also well known, however, that bio-impedance measurements can be confounded by signals not directly related to the desired physiology to be measured. For example, a measurement of impedance from a unipolar tip electrode in the right ventricular apex will contain signal components related to respiration, and right ventricular, left ventricular, and aortic hemodynamics. Filtering of the signal can help to isolate the various desired signals, but the filtering required to accurately isolate the desired signals are often not feasible in an implantable cardiac rhythm management device.

It is also known that localization of the desired signals is improved by making proper choice of electrode configurations between which impedance measurements are made. For example, a transchamber impedance technique is known wherein impedance measurements are made between electrodes in the right atrium and right ventricle to assist in isolating the right ventricular hemodynamics.

The advent of cardiac leads for delivering therapy to the left-side of the heart which are often placed in the coronary sinus and great cardiac vein require new techniques for measurement of functional parameters of, or associated with, a heart. As will be seen hereinafter, the present invention addresses those needs.

SUMMARY

Methods of and systems for measuring impedance, and for measuring at least one physiological parameter for assessing a patient's cardiac condition based on left heart impedance measurements are described. Various embodiments establish a current flow through a left side of the heart and measure a voltage between a first location on or in the left side of the heart and a second location

within the human body while establishing the current flow. The inventive techniques and systems can be used for, among other things, measuring progression or regression of myocardial failure, dilation, or hypertrophy, pulmonary congestion, myocardial contractility, or ejection fraction. The measured voltage, related to left heart impedance, can be used to monitor patient condition for diagnostic purposes or to adapt pacing or defibrillation therapy. Therapy adaptation can include controlling pacing modes, pacing rates, or interchamber pacing delays, for example.

Various embodiments still further provide systems for measuring at least one physiological parameter of a patient's cardiac condition wherein the system includes a current source for establishing a current flow through a left side of the heart, measurement circuitry that measures a voltage between a first location on or in the left side of the heart and a second location within the human body while establishing the current flow, and control circuitry that responds to the measured voltage for adjusting stimulation therapy. Measurements of the physiological parameter(s) can take place utilizing many different electrode polarity configurations, e.g. bipolar, tripolar, and quadrapolar configurations.

BRIEF DESCRIPTION OF THE DRAWINGS

The following description is of the best mode presently contemplated for practicing the invention. This description is not to be taken in a limiting sense but is made merely for the purpose of describing the general principles of the invention. The scope of the invention should be ascertained with reference to the issued claims.

FIG. 1 is a simplified diagram illustrating an implantable stimulation device in electrical communication with at least three leads implanted into a patient's heart for delivering multi-chamber stimulation and shock therapy;

FIG. 2 is a functional block diagram of a multi-chamber implantable stimulation device illustrating exemplary basic elements of a stimulation device which can provide cardioversion, defibrillation and/or pacing stimulation in up to four chambers of the heart;

FIG. 3 is a reproduction of the patient's heart shown in FIG. 1 illustrating a an electrode configuration that is suitable for use in ascertaining an impedance measure in accordance with one embodiment.

FIG. 4 is a reproduction of the patient's heart shown in FIG. 1 illustrating a an electrode configuration that is suitable for use in ascertaining an impedance measure in accordance with one embodiment.

FIG. 5 is a reproduction of the patient's heart shown in FIG. 1 illustrating a an electrode configuration that is suitable for use in ascertaining an impedance measure in accordance with one embodiment.

FIG. 6 is a reproduction of the patient's heart shown in FIG. 1 illustrating a an electrode configuration that is suitable for use in ascertaining an impedance measure in accordance with one embodiment.

FIG. 7 is a reproduction of the patient's heart shown in FIG. 1 illustrating a an electrode configuration that is suitable for use in ascertaining an impedance measure in accordance with one embodiment.

FIG. 8 is a reproduction of the patient's heart shown in FIG. 1 illustrating a an electrode configuration that is suitable for use in ascertaining an impedance measure in accordance with one embodiment.

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FIG. 9 is a reproduction of the patient's heart shown in FIG. 1 illustrating a an electrode configuration that is suitable for use in ascertaining an impedance measure in accordance with one embodiment.

FIG. 10 is a reproduction of the patient's heart shown in FIG. 1 illustrating a an electrode configuration that is suitable for use in ascertaining an impedance measure in accordance with one embodiment.

FIG. 11 is a reproduction of the patient's heart shown in FIG. 1 illustrating a an electrode configuration that is suitable for use in ascertaining an impedance measure in accordance with one embodiment.

FIG. 12 is a reproduction of the patient's heart shown in FIG. 1 illustrating a an electrode configuration that is suitable for use in ascertaining an impedance measure in accordance with one embodiment.

FIG. 13 is a reproduction of the patient's heart shown in FIG. 1 illustrating a an electrode configuration that is suitable for use in ascertaining an impedance measure in accordance with one embodiment.

FIG. 14 is a reproduction of the patient's heart shown in FIG. 1 illustrating a an electrode configuration that is suitable for use in ascertaining an impedance measure in accordance with one embodiment.

FIG. 15 is a reproduction of the patient's heart shown in FIG. 1 illustrating a an electrode configuration that is suitable for use in ascertaining an impedance measure in accordance with one embodiment.

FIG. 16 is a reproduction of the patient's heart shown in FIG. 1 illustrating a an electrode configuration that is suitable for use in ascertaining an impedance measure in accordance with one embodiment.

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FIG. 17 is a reproduction of the patient's heart shown in FIG. 1 illustrating a an electrode configuration that is suitable for use in ascertaining an impedance measure in accordance with one embodiment.

FIG. 18 is a reproduction of the patient's heart shown in FIG. 1 illustrating a an electrode configuration that is suitable for use in ascertaining an impedance measure in accordance with one embodiment.

FIG. 19 is a reproduction of the patient's heart shown in FIG. 1 illustrating a an electrode configuration that is suitable for use in ascertaining an impedance measure in accordance with one embodiment.

FIG. 20 is a reproduction of the patient's heart shown in FIG. 1 illustrating a an electrode configuration that is suitable for use in ascertaining an impedance measure in accordance with one embodiment.

FIG. 21 is a reproduction of the patient's heart shown in FIG. 1 illustrating a an electrode configuration that is suitable for use in ascertaining an impedance measure in accordance with one embodiment.

FIG. 22 is a reproduction of the patient's heart shown in FIG. 1 illustrating a an electrode configuration that is suitable for use in ascertaining an impedance measure in accordance with one embodiment.

DETAILED DESCRIPTION

The following description is of the best mode presently contemplated for practicing the invention. This description is not to be taken in a limiting sense but is made merely for the purpose of describing the general principles of the invention. The scope of the invention should be ascertained with reference to the

issued claims. In the description of the invention that follows, like numerals or reference designators will be used to refer to like parts or elements throughout.

Exemplary Stimulation Device

The following description sets forth but one exemplary stimulation device that is capable of being used in connection with the various embodiments that are described below. It is to be appreciated and understood that other stimulation devices, including those that are not necessarily implantable, can be used and that the description below is given, in its specific context, to assist the reader in understanding, with more clarity, the inventive embodiments described herein.

FIG. 1 illustrates a stimulation device 10 in electrical communication with a patient's heart 12 suitable for delivering multi-chamber stimulation and shock therapy. The portions of the heart 10 illustrated include the right ventricle 14, the right atrium 15, the left ventricle 17, and the left atrium 18. As used herein, the left-side of the heart is meant to denote the portions of the heart encompassing the left ventricle 17 and the left atrium 18 and those portions of the coronary sinus, great cardiac vein, and its associated tributaries, which are adjacent the left atrium and left ventricle. As will be seen hereinafter, the device 10 includes a system for measuring a physiological parameter, and more particularly, the left ventricular impedance corresponding to contraction of the heart 12, in accordance with various embodiments described in further detail below.

To sense atrial cardiac signals and to provide right atrial chamber stimulation therapy, the stimulation device 10 is coupled to an implantable right atrial lead 20 having at least an atrial tip electrode 22, and preferably a right atrial

ring electrode 23, which typically is implanted in the patient's right atrial appendage.

To sense left atrial and ventricular cardiac signals and to provide left-chamber pacing therapy, the stimulation device 10 is coupled to a "coronary sinus" lead 24 designed for placement in the "coronary sinus region" via the coronary sinus os so as to place one or more distal electrodes adjacent to the left ventricle 17 and one or more proximal electrodes adjacent to the left atrium 18. As used herein, the phrase "coronary sinus region" refers to the vasculature of the left ventricle, including any portion of the coronary sinus, great cardiac vein, left marginal vein, left posterior ventricular vein, middle cardiac vein, and/or small cardiac vein or any other cardiac vein accessible by the coronary sinus.

Accordingly, the coronary sinus lead 24 is designed to receive atrial and ventricular cardiac signals and to deliver: left ventricular pacing therapy using, for example, a left ventricular tip electrode 25 and a left ventricular ring electrode 26; left atrial pacing therapy using, for example, a first and second left atrial ring electrode, 27 and 28; and shocking therapy using at least a left atrial coil electrode 29. For a complete description of a coronary sinus lead, refer to U.S. Patent Application No. 09/457,277, titled "A Self-Anchoring, Steerable Coronary Sinus Lead" (Pianca et al.); and U.S. Patent No. 5,466,254, titled "Coronary Sinus Lead with Atrial Sensing Capability" (Helland), which patents are hereby incorporated herein by reference.

The stimulation device 10 is also shown in electrical communication with the patient's heart 12 by way of an implantable right ventricular lead 30 having a right ventricular tip electrode 32, a right ventricular ring electrode 34, a right ventricular (RV) coil electrode 36, and an SVC coil electrode 38. Typically, the

right ventricular lead 30 is transvenously inserted into the heart 12 so as to place the right ventricular tip electrode 32 in the right ventricular apex so that the RV coil electrode 36 will be positioned in the right ventricle and the SVC coil electrode 38 will be positioned in the superior vena cava. Accordingly, the right ventricular lead 30 is capable of receiving cardiac signals, and delivering stimulation in the form of pacing and shock therapy to the right ventricle 14.

FIG. 2 illustrates a simplified block diagram of the multi-chamber implantable stimulation device 10, which is capable of treating both fast and slow arrhythmias with stimulation therapy, including cardioversion, defibrillation, and pacing stimulation. While a particular multi-chamber device is shown, this is for illustration purposes only, and one of skill in the art could readily duplicate, eliminate or disable the appropriate circuitry in any desired combination to provide a device capable of treating the appropriate chamber(s) with cardioversion, defibrillation and/or pacing stimulation. In addition, it will be appreciated and understood that various processing steps about to be described can be implemented in the form of software instructions that are resident on a computer-readable media that is located on the stimulation device. Accordingly, aspects of the invention described herein extend to all forms of computer-readable media, whether on the stimulation device or not, when such media contains instructions that, when executed by one or more processors, implement the methods described herein.

The stimulation device 10 includes a housing 40 which is often referred to as "can", "case" or "case electrode", and which may be programmably selected to act as the return electrode for all "unipolar" modes. The housing 40 may further be

used as a return electrode alone or in combination with one or more of the coil electrodes 29, 36, or 38, for shocking purposes.

The housing 40 further includes a connector (not shown) having a plurality of terminals, 42, 43, 44, 45, 46, 47, 48, 52, 54, 56, and 58 (shown schematically and, for convenience, the names of the electrodes to which they are connected are shown next to the terminals). While it is recognized that current devices are limited to the number of terminals due to International Standards, one of skill in the art could readily eliminate some of the terminals/electrodes to fit in the existing device configurations and permit programmability to select which terminals connect to which electrodes. However, in the near future, the standards may change to permit multi-polar in-line connectors, and multiple feedthroughs connectors could readily be manufactured to accommodate the configuration shown in FIG. 2.

As such, to achieve right atrial sensing and pacing, the connector includes at least a right atrial tip terminal 42 and a right atrial ring terminal 43, adapted for connection to the atrial tip electrode and ring electrodes 22 and 23, respectively.

To achieve left chamber sensing, pacing and/or shocking, the connector includes at least a left ventricular tip terminal 44, a left ventricular ring electrode 45, a first left atrial ring terminal 46, a second left atrial ring terminal 47, and a left atrial shocking terminal 48, which are adapted for connection to the left ventricular tip electrode 25, left ventricular ring 26, the first left atrial tip electrode 27, the second left atrial ring electrode 28, and the left atrial coil electrode 29, respectively.

To support right chamber sensing, pacing and/or shocking, the connector further includes a right ventricular tip terminal 52, a right ventricular ring terminal

54, a right ventricular (RV) shocking terminal 56, and an SVC shocking terminal 58, which are adapted for connection to the right ventricular tip electrode 32, right ventricular ring electrode 34, the RV coil electrode 36, and the SVC coil electrode 38, respectively.

At the core of the stimulation device 10 is a programmable microcontroller or microprocessor 60 that controls the various modes of stimulation therapy. As is well known in the art, the microcontroller 60 typically includes a microprocessor, or equivalent control circuitry, designed specifically for controlling the delivery of stimulation therapy, and may further include RAM or ROM memory, logic and timing circuitry, state machine circuitry, and I/O circuitry. Typically, the microcontroller 60 includes the ability to process or monitor input signals (data) as controlled by a program code stored in a designated block of memory. The details of the design and operation of the microcontroller 60 are not critical to the present invention. Rather, any suitable microcontroller 60 may be used that carries out the functions described herein. The use of microprocessor-based control circuits for performing timing and data analysis functions are well known in the art.

As shown in FIG. 2, an atrial pulse generator 70 and a ventricular pulse generator 72 generate pacing stimulation pulses for delivery by the right atrial lead 20, the right ventricular lead 30, and/or the coronary sinus lead 24 via a switch bank 74. It is understood that in order to provide stimulation therapy in each of the four chambers of the heart, the atrial pulse generator 70 and the ventricular pulse generator 72 may include dedicated, independent pulse generators, multiplexed pulse generators, or shared pulse generators. The atrial pulse generator 70 and the ventricular pulse generator 72 are controlled by the

microcontroller 60 via appropriate control signals 76 and 78, respectively, to trigger or inhibit the stimulation pulses.

The microcontroller 60 further includes timing control circuitry 79 which is used to control the timing of such stimulation pulses (e.g., pacing rate, atrio-ventricular (AV) delay, atrial interconduction (A-A) delay, or ventricular interconduction (V-V) delay, etc.), as well as to keep track of the timing of refractory periods, PVARP intervals, noise detection windows, evoked response windows, alert intervals, marker channel timing (via marker channel logic 81), etc., which is well known in the art.

The switch bank 74 includes a plurality of switches for connecting the desired electrodes to the appropriate I/O circuits, thereby providing complete electrode programmability. Accordingly, the switch bank 74, in response to a control signal 80 from the microcontroller 60, determines the polarity of the stimulation pulses (e.g. unipolar, bipolar, combipolar, etc.) and various shocking vectors by selectively closing the appropriate combination of switches (not shown) as is known in the art.

Atrial sensing circuits 82 and ventricular sensing circuits 84 may also be selectively coupled to the right atrial lead 20, coronary sinus lead 24, and the right ventricular lead 30, through the switch bank 74, for detecting the presence of cardiac activity in each of the four chambers of the heart. Accordingly, the atrial and ventricular sensing circuits 82 and 84 may include dedicated sense amplifiers, multiplexed amplifiers, or shared amplifiers. The switch bank 74 determines the "sensing polarity" of the cardiac signal by selectively closing the appropriate switches. In this way, the clinician may program the sensing polarity independent of the stimulation polarity.

The atrial sensing circuit 82 or the ventricular sensing circuit 84 preferably employ one or more low power, precision amplifiers with programmable gain and/or automatic gain control, bandpass filtering, and a threshold detection circuit, to selectively sense the cardiac signal of interest. The automatic gain control enables the stimulation device 10 to deal effectively with the difficult problem of sensing the low amplitude signal characteristics of atrial or ventricular fibrillation. The outputs of the atrial and ventricular sensing circuits, 82 and 84, are connected to the microcontroller 60 for triggering or inhibiting the atrial and ventricular pulse generators, 70 and 72, respectively, in a demand fashion, in response to the absence or presence of cardiac activity, respectively, in the appropriate chambers of the heart.

For arrhythmia detection, the stimulation device 10 utilizes the atrial and ventricular sensing circuits, 82 and 84, to sense cardiac signals for determining whether a rhythm is physiologic or pathologic. As used herein "sensing" is reserved for the noting of an electrical signal, and "detection" is the processing of these sensed signals and noting the presence of an arrhythmia. The timing intervals between sensed events (e.g. P-waves, R-waves, and depolarization signals associated with fibrillation which are sometimes referred to as "F-waves" or "Fib-waves") are then classified by the microcontroller 60 by comparing them to a predefined rate zone limit (e.g. bradycardia, normal, low rate VT, high rate VT, and fibrillation rate zones) and various other characteristics (e.g. sudden onset, stability, physiologic sensors, and morphology, etc.) in order to determine the type of remedial therapy that is needed (e.g. bradycardia pacing, anti-tachycardia pacing, cardioversion shocks or defibrillation shocks, collectively referred to as "tiered therapy").

Cardiac signals are also applied to the inputs of an analog-to-digital (A/D) data acquisition system 90. The data acquisition system 90 is configured to acquire intracardiac electrogram signals, convert the raw analog data into digital signals, and store the digital signals for later processing and/or telemetric transmission to an external device 102. The data acquisition system 90 is coupled to the right atrial lead 20, the coronary sinus lead 24, and the right ventricular lead 30 through the switch bank 74 to sample cardiac signals across any pair of desired electrodes.

The microcontroller 60 is further coupled to a memory 94 by a suitable data/address bus 96, wherein the programmable operating parameters used by the microcontroller 60 are stored and modified, as required, in order to customize the operation of the stimulation device 10 to suit the needs of a particular patient. Such operating parameters define, for example, pacing pulse amplitude, pulse duration, electrode polarity, rate, sensitivity, automatic features, arrhythmia detection criteria, and the amplitude, waveshape and vector of each shocking pulse to be delivered to the patient's heart 12 within each respective tier of therapy.

Advantageously, the operating parameters of the stimulation device 10 may be non-invasively programmed into the memory 94 through a telemetry circuit 100 in telemetric communication with the external device 102, such as a programmer, transtelephonic transceiver, or a diagnostic system analyzer. The telemetry circuit 100 is activated by the microcontroller 60 by a control signal 106. The telemetry circuit 100 advantageously allows intracardiac electrograms and status information relating to the operation of the stimulation device 10 (as contained in the microcontroller 60 or memory 94) to be sent to the external device 102 through the established communication link 104.

In a preferred embodiment, the stimulation device 10 further includes a physiologic sensor 108, commonly referred to as a "rate-responsive" sensor because it is typically used to adjust pacing stimulation rate according to the exercise state of the patient. However, the physiological sensor 108 may further be used to detect changes in cardiac output, changes in the physiological condition of the heart, or diurnal changes in activity (e.g. detecting sleep and wake states). A physiological parameter of the heart, which may be measured to optimize such pacing and to indicate when such pacing may be inhibited or terminated is the stroke volume of the heart. Accordingly, the microcontroller 60 responds by adjusting the various pacing parameters (such as rate, AV Delay, A-A Delay, V-V Delay, etc.) at which the atrial and ventricular pulse generators, 70 and 72, generate stimulation pulses.

The stimulation device 10 additionally includes a power source such as a battery 110 that provides operating power to all the circuits shown in FIG. 2. For the stimulation device 10, which employs shocking therapy, the battery 110 must be capable of operating at low current drains for long periods of time, and also be capable of providing high-current pulses (for capacitor charging) when the patient requires a shock pulse. The battery 110 must preferably have a predictable discharge characteristic so that elective replacement time can be detected. Accordingly, the stimulation device 10 can employ lithium/silver vanadium oxide batteries.

It can be a primary function of the stimulation device 10 to operate as an implantable cardioverter/defibrillator (ICD) device. That is, it can detect the occurrence of an arrhythmia, and automatically apply an appropriate electrical shock therapy to the heart aimed at terminating the detected arrhythmia. To this

end, the microcontroller 60 further controls a shocking circuit 116 by way of a control signal 118. The shocking circuit 116 generates shocking pulses of low (up to 0.5 joules), moderate (0.5 - 10 joules), or high (11 to 40 joules) energy, as controlled by the microcontroller 60. Such shocking pulses are applied to the patient's heart through at least two shocking electrodes, and as shown in this embodiment, selected from the left atrial coil electrode 29, the RV coil electrode 36, and/or the SVC coil electrode 38 (FIG. 1). As noted above, the housing 40 may act as an active electrode in combination with the RV electrode 36, or as part of a split electrical vector using the SVC coil electrode 38 or the left atrial coil electrode 29 (i.e., using the RV electrode as the common electrode).

Cardioversion shocks are generally considered to be of low to moderate energy level (so as to minimize pain felt by the patient), and/or synchronized with an R-wave and/or pertaining to the treatment of tachycardia. Defibrillation shocks are generally of moderate to high energy level (i.e., corresponding to thresholds in the range of 5-40 joules), delivered asynchronously (since R-waves may be too disorganized), and pertaining exclusively to the treatment of fibrillation. Accordingly, the microcontroller 60 is capable of controlling the synchronous or asynchronous delivery of the shocking pulses.

As further shown in Fig. 2, the stimulation device 10 is shown as having an impedance measuring circuit 120 including an impedance measuring current source 112 and a voltage measuring circuit 90 (shown in FIG. 2 as an A/D converter), which is enabled by the microcontroller 60 by a control signal 114 for providing stroke volume measurements of the heart. The current source 112 preferably provides an alternating or pulsed excitation current. The voltage

measuring circuitry 90 may also take the form of, for example, a differential amplifier.

The uses for an impedance measuring circuit 120 include, but are not limited to, lead impedance surveillance during the acute and chronic phases for proper lead positioning or dislodgment; detecting operable electrodes and automatically switching to an operable pair if dislodgment occurs; measuring a respiration parameter (for example, tidal volume, respiration rate, minute ventilation or volume, abnormal or periodic breathing); measuring thoracic impedance for determining shock thresholds and shock timing (corresponding to the diastolic time); detecting when the device has been implanted; measuring a cardiac parameter (such as, stroke volume, wall thickness, left ventricular volume, etc.); and detecting the opening of the valves, etc. In the present embodiment, the impedance measuring circuit is used to monitor left heart disease and provides appropriate stimulation therapy, such as altering rate, AV , A-A , or V-V delays. The impedance measuring circuit 120 is advantageously coupled to the switch bank 74 so that any desired electrode may be used. Impedance may also be useful in verifying hemodynamic collapse to confirm that ATP has failed and/or VF has begun.

The microcontroller 60 is coupled to the voltage measuring circuit 90 and the current source 112 for receiving a magnitude of the established current and a magnitude of the monitored voltage. The microcontroller 60, operating under program instructions, divides the magnitude of the monitored or measured voltage by the magnitude of the established current to determine an impedance value. Once the impedance signals are determined, they may be delivered to the memory 94 for storage and later retrieved by the microcontroller 60 for therapy adjustment

or telemetry transmission. The telemetry circuitry receives the impedance values from the microcontroller 60 and transmits them to the external programmer. The impedance value may then be monitored by the patient's physician to enable the physician to track the patient's condition.

The impedance measuring circuit 120 is advantageously coupled to the switch bank 74 so that any desired electrode may be used. The current source 112 may be programmably configured between a desired pair of electrodes, and the voltage measuring circuit 90 may be programmably configured between the same or preferably a different pair of electrodes.

Exemplary Inventive Embodiments Overview

In the embodiments below, various configurations of electrodes are provided that permit measurements of left ventricular function to be made for both monitoring and therapy delivery. The different configurations can have a variety of polarities. For example, bipolar, tripolar and quadrapolar configurations can be used. Bipolar configurations are configurations that utilize any two suitable electrodes; tripolar configurations are configurations that use any three suitable electrodes; and quadrapolar configurations are configurations that use any four suitable configurations. The different configurations can be used to measure one or more physiological parameters for assessing or determining a patient's cardiac condition based on left heart impedance measurements. In the discussion that follows, certain specific electrode configurations are described to provide non-limiting examples of various bipolar, tripolar, and quadrapolar configurations that can be used to facilitate measurement of left ventricular function and the measurement of other parameters associated with heart function.

Respiration

In conjunction with ventricular pacing of the heart, one parameter associated with the heart which is prominent in ascertaining the effectiveness of the cardiac pacing is respiration (or a respiration parameter, for example, tidal volume, respiration rate, minute ventilation or volume, abnormal or periodic breathing). This requires ascertaining the condition of the lung tissue and may also be measured by the device 10 illustrated in FIG. 3. This may be preferably accomplished by sourcing the current between the housing 40 and right ventricular coil electrode 36 while measuring the voltage between the left ventricular tip electrode 25 and housing 40.

One limitation in the use of a pacing electrode, or a pacing electrode pair, in the cardiac vein is that the local impedance is influenced by many factors. With the system illustrated in FIG. 4, a three-point impedance measurement is obtained which is less affected by the local impedance of the electrode or electrodes in the great vein. As a result, an accurate measure of the left ventricular impedance is obtained to provide corresponding accurate monitoring of stroke volume and the respiration parameter.

In measuring the respiration parameter, a current path is established between the left ventricular tip electrode 25 and the housing 40. Once established, the voltage measuring circuit measures the voltage between the left ventricular ring electrode 26 and the housing 40. This effectively provides an impedance measurement corresponding to the respiration parameter. The resulting measured voltage signal will have both cardiac and respiratory components. However, the

cardiac component will be smaller than that from intracardiac electrodes and can be readily filtered in a manner known in the art.

FIG. 5 shows another electrode configuration that can be used to measure impedance. In this configuration, a current path is established between left atrial ring electrode 28 and the housing 40. The voltage measuring circuit then measures the voltage between the left atrial ring electrode 27 and the housing 40.

FIG. 6 shows another electrode configuration that can be used to measure impedance. In this configuration, a current path is established between left atrial coil electrode 29 and the housing 40. The voltage measuring circuit then measures the voltage between the left atrial ring electrode 27 and the housing 40.

FIG. 7 shows a tripolar electrode configuration that can be used to measure impedance. In this configuration, a current path is established between right ventricular ring electrode 34 and the housing 40. The voltage measuring circuit then measures the voltage between the left atrial ring electrode 27 and the housing 40.

Alternatively, as will be appreciated by those skilled in the art, left atrial ring electrodes 27 and 28 can be utilized for the respiration parameter measurements. In this case, shown in FIG. 8, the electrical current path is established between the first atrial ring electrode 27 and the housing 40 and the resulting voltage is measured between the second atrial ring electrode 28 and the housing 40. As will also be appreciated by those skilled in the art, an alternative embodiment could employ a single electrode in a cardiac vein with appropriate filtering to extract the respiration parameter component of the impedance signal.

Left Ventricular Wall Dynamics

In an alternate embodiment, shown in FIG. 9, the device 10 can be coupled to a different electrode configuration for measuring left ventricular wall dynamics. Here it will be seen that the current source 112 is coupled between the left ventricular ring electrode 26 and the left ventricular tip electrode 25. The voltage measuring circuit 90 is also coupled between left ventricular ring electrode 26 and left ventricular tip electrode 25. Since the left ventricular electrodes 25 and 26 are preferably positioned so as to be located on the left ventricular free wall, the voltage signal measured by the voltage measuring circuit 90 will predominantly represent myocardium impedance for measuring left ventricular wall dynamics, such as the wall thickness.

FIG. 10 shows an alternate bipolar electrode configuration that can be utilized to measure impedance for measuring left ventricular wall dynamics. In this embodiment, the current source 112 is coupled between the left atrial ring electrode 27 and the left ventricular tip electrode 25. The voltage measuring circuit 90 is coupled between the left atrial ring electrode 27 and the left ventricular tip electrode 25.

FIG. 11 shows an alternate tripolar electrode configuration that can be utilized to measure impedance for measuring left ventricular wall dynamics. In this embodiment, the current source 112 is coupled between the left atrial ring electrode 27 and the left ventricular tip electrode 25. The voltage measuring circuit 90 is coupled between the left atrial ring electrode 28 and the left ventricular tip electrode 25.

FIG. 12 shows an alternate quadrapolar electrode configuration that can be utilized to measure impedance for measuring left ventricular wall dynamics. In

this embodiment, the current source 112 is coupled between the left atrial ring electrode 28 and the left ventricular tip electrode 25. The voltage measuring circuit 90 is coupled between the left atrial ring electrode 27 and the left ventricular ring electrode 26.

Alternatively, the current source 112 can be coupled between a right ventricular electrode 32 or 34 and the housing 40 with voltage measurement still performed between electrodes 26 and 25 as shown in FIG. 13. As will be appreciated by those skilled in the art, an alternative embodiment could employ a single electrode within a cardiac vein on the left ventricular free wall and appropriate filtering to extract the cardiac component in the impedance signal.

FIG. 14 shows an alternate tripolar electrode configuration that can be utilized to measure impedance for measuring left ventricular wall dynamics. In this embodiment, the current source 112 is coupled between the right ventricular ring electrode 34 and the housing 40. The voltage measuring circuit 90 is coupled between the left atrial ring electrodes 27, 28.

FIG. 15 shows an alternate electrode configuration that can be utilized to measure impedance for measuring left ventricular wall dynamics. In this embodiment, the current source 112 is coupled between the right ventricular ring electrode 34 and the housing 40. The voltage measuring circuit 90 is coupled between the left atrial ring electrode 28 and the left ventricular ring electrode 26.

Left Ventricular Volume Measurements

The current source 112 and voltage measuring circuit 90 may be employed in still further different configurations that facilitate left ventricular volume measurements. Here it will be seen that the left ventricular volume measurements

are made with electrode pairs which are selected to measure a cross-section of the left ventricle. This can be done by determining the trans-chamber impedance.

For example, FIG. 16 shows a configuration that can be utilized to monitor stroke volume. In this configuration, the current source 112 can be configured to provide an alternating current between the housing 40 and the right ventricular coil electrode 36. As this current is established, the voltage across the left ventricle is measured between the left ventricular tip electrode 25 and the right ventricular coil electrode 36. This gives an accurate measure of the left ventricular impedance and will provide an accurate contraction signature.

FIG. 17 shows another configuration that can be utilized to determine trans-chamber impedance. Here, the current source 112 is coupled between the right ventricular tip electrode 32 and the left ventricular ring electrode 26, while the voltage measuring circuit 90 is coupled between the right ventricular ring electrode 34 and the left ventricular tip electrode 25.

FIG. 18 shows a bipolar configuration that can be utilized to determine trans-chamber impedance. Here, the current source 112 is coupled between the right ventricular ring electrode 34 and the left ventricular ring electrode 26, and the voltage measuring circuit 90 is coupled between the right ventricular ring electrode 34 and the left ventricular ring electrode 26.

In accordance with the embodiment shown in FIG. 18, the current source 112 is coupled between the right ventricular ring electrode 34 and the left ventricular ring electrode 26, while the voltage measuring circuit 90 is coupled between the right ventricular ring electrode 34 and the left ventricular tip electrode 25.

Preferably, the voltage measuring circuitry 90 measures the voltage between the right ventricular electrode 32 or 34 which was not used in the establishing of the electrical current path and the left ventricular tip electrode 25. The voltage signal thus measured will be representative of the cross-section of the left ventricle and yield an accurate representation of the left ventricular volume.

In yet another alternative embodiment for measuring left ventricular volume (a quadrapolar configuration), shown in FIG. 20, it will be noted that the current source 112 is coupled between the right ventricular ring electrode 34 and the first left atrial ring electrode 27, while the voltage measuring circuit 90 is coupled between the right ventricular tip electrode 32 and the second left atrial ring electrode 28.

Alternatively, shown in FIG. 21, the current source 112 can be coupled between the right ventricular ring electrode 34 and the housing 40, while the voltage measuring circuit 90 is coupled between the right ventricular tip electrode 32 and the second left atrial ring electrode 28.

In yet another embodiment, a quadrapolar configuration shown in FIG. 22, is provided for measuring the left ventricular volume. Here, the current source 112 establishes an electrical current between the right ventricular ring electrode 34 and the first left atrial ring electrode 27. While this current is established, the voltage measuring circuit 90 measures the voltage between the right ventricular tip electrode 32 and the second left atrial ring electrode 28 . The resulting voltage signal measured by the voltage measuring circuit 90 will represent the impedance across the cross-section of the left ventricle to provide an accurate representation of the left ventricular volume.

The impedance measurements may be obtained by establishing an electrical current between the electrode of an electrode pair and measuring the voltage between the electrode pair during the current establishment. Mechanical activation of an associated chamber will cause a significant deflection in the resulting voltage signal or impedance. This provides a valuable tool for monitoring systolic and diastolic time intervals of the heart. For example, an impedance measurement from a chamber may be taken to indicate the mechanical activation of that chamber as for example the electrode pair, 32 and 34, in the right ventricle to indicate the timing of the right ventricular contraction and the bipolar pair, 25 and 26, to indicate the timing of the left ventricular contraction. From the different times of mechanical activation, systolic and diastolic time intervals may be ascertained by comparing these times to those based on electrogram measurements.

As can be seen from the foregoing, the present invention provides a system and method for measuring a physiological parameter of, or associated with, a patient's a heart. In each of the foregoing embodiments, a current flow is established through a left side of the heart and a voltage is measured between a first location on or in the left side of the heart and a second location within the human body while establishing the current flow. This preferably includes implanting a first electrode within the coronary sinus and/or a vein of the heart, implanting a second electrode within the body, establishing a current within the body, and measuring a voltage between the first and second electrodes while establishing the current flow. As a result, impedance measurements may be obtained which provide valuable information for the patient's physician to diagnostically monitor and use which are indicative of physiological parameters

of, or associated with, the heart for those patients which require cardiac rhythm management associated with the left side of the heart.

Although the invention has been described in language specific to structural features and/or methodological steps, it is to be understood that the invention defined in the appended claims is not necessarily limited to the specific features or steps described. Rather, the specific features and steps are disclosed as preferred forms of implementing the claimed invention.